CLAIMS

1. Agglomerates in crystalline form comprising one or more ß-lactam compounds, wherein at least one ß-lactam compound has a high water affinity, and optionally containing one or more excipients, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

2. Agglomerates according to claim 1, wherein the agglomerates are substantially free from non-agglomerated ß-lactam crystals.

3. Agglomerates according to claim 1 or 2, wherein at least one ß-lactam compound is clavulanic acid.

4. Agglomerates according to any one of the claims 1-3, wherein the ß-lactam compound is potassium clavulanate.

5. Agglomerates according to claim 4, consisting of only potassium clavulanate.

6. Agglomerates according to claim 4 further comprising amoxicillin.

7. Agglomerates according to anyone of the claims 1-4 or 6, wherein the excipients are microcrystalline cellulose, preferably Avicel®, or silica, preferably Syloid® or Aerosil®.

8. Agglomerates according to anyone of the claims 1-7, wherein the agglomerates have an average particle size between about 1 μm and 1500 μm, preferably between about 500 μm and 1500 μm, more preferably between 800 μm and 1200 μm, or preferably between 1 μm and 300 μm, more preferably between 1 μm and 200 μm.

9. Agglomerates according to anyone of the claims 1-8 in sterile form.

10. A process for the preparation of crystallised agglomerates as defined in anyone of the claims 1-9, wherein the agglomerates are produced in a liquid phase by applying stirring devices.

11. A process according to claim 10, wherein the liquid phase comprises a solution or suspension of at least one corresponding ß-lactam compound in a solvent or in a mixture of solvents together with one or more anti-solvents.

12. A process according to claim 11, wherein the ratio of the weight of the solution containing ß-lactam compound to the anti-solvent is about 0.05 to 10 wt.%.

13. A process according to claim 11 or 12, wherein the solvent is selected from the group consisting of water, alcohol, ketone and ester or a mixture thereof, whereby water is present.

14. A process according to anyone of the claims 10-13, wherein the anti-solvent is a ketone, like acetone, methylethylketone, methylisobutylketone or an ester, like methyl acetate, ethyl acetate, isopropyl acetate, butyl acetate or an alcohol, like 1-propanol, 1-butanol, 2-butanol, 2-methyl-1-propanol or a mixture of these solvents, optionally containing water.

15. A process according to anyone of the claims 10-14, wherein one or more stirring devices are used to crystallise, agglomerate and/or deagglomerate the ß-lactam compound and optionally classification and blending with excipients and/or another ß-lactam compound in a batch or continuous operation, in one or more units.

16. A process according to claim 15, wherein the process is performed by applying stirring devices in one or more vessels, in-line mixers or a combination thereof.

17. A process according to claim 15 or 16, wherein a high shear mixer is used as stirring device.

Sub A3

18. A process according to anyone of the claims 10-17, characterised by the preparation of agglomerates with various particle sizes, by further using a combination and permutation of different stirring devices and their speed, the type and amount of the solvents used and the way of mixing of one or more solvents and anti-solvents.

19. A process according to claim 18, characterised by the preparation of agglomerates with various particle sizes, by further using a nozzle-sprayer for the solution.

20. A process according to any one of the claims 10-19, characterised by dissolving one or more corresponding ß-lactams in a solvent, adjusting the pH to about neutral and mixing with the anti-solvent.

21. A pharmaceutical formulation comprising the agglomerates of anyone of the claims 1-9 and one or more pharmaceutical acceptable excipients.

22. A pharmaceutical formulation comprising amoxicillin, preferably amoxicillin trihydrate and the crystalline agglomerates of potassium clavulanate as defined in claim 5, and optionally one or more pharmaceutically acceptable inert excipients.

Sub A3

23. A pharmaceutical formulation, comprising a mixture of amoxicillin trihydrate and crystalline agglomerates of potassium clavulanate and one or more pharmaceutically acceptable inert excipients as defined in claim 4.

24. Pharmaceutical dosage form comprising a pharmaceutical formulation of anyone of the claims 21-23.

add A4

add B1